Internal Audit Reporting Document

Audit Date: 2018

Department/Unit Audited: BMT/CT Program

Audit Title: CIBMTR Internal Audit 20 Pre- and Post-Transplant Essential Data (TED) Forms

Auditor: _____ Clinical Trials Project Manager (CRA III)

Audit Plan: Manual audit of electronically submitted TED forms for Autologous and Allogeneic Transplants occurred in 2017. Audit of 10 patients (sample size >10%) was planned for this audit. Audit was intended to: 1) assess accuracy of reported information, 2) ensure patient consents were signed, and 3) source documentation is present in patient chart.

Type & Audit Period: Annual audit of electronically submitted TED forms for transplants occurred in 2017.

Audit Purpose and Scope: In alignment with the FACT Standard B4.8.3.3, *accuracy of data contained in the Transplant Essential Data Forms of the CIBMTR or the Minimum Essential Data-A Forms of the EBMT* is audited annually. The purpose of this internal audit was to evaluate the accuracy of TED forms for 10 patients who received Allogeneic or Autologous transplants in the calendar year 2017. The scope of this audit was comprehensive and included a review of all data points electronically submitted to CIBMTR in FormsNet3.

Audit Summary:

10 patients (approximately 10%) were selected for this audit. Selected patients are listed in Table 1. Donor type (allogeneic or autologous) and stem cell source (PBSC, BM or CBU) are indicated as well. For all patients listed in Table 1, 100% of data (all fields for all forms) submitted to CIBMTR were audited. Critical Fields were defined per CIBMTR Forms Manual: Appendix Y, version 1.

Assigned auditor was Clinical Trials Project Manager. Auditor verified entries for all fields (included all critical fields) against the source documents. Consents forms were verified for completion.

% Total Error and % Critical errors were calculated separately as:

% Total Error = (Total number of errors/Total fields audited)*100%

% Critical Errors = (Total number of critical errors/Total critical fields audited)*100%

Findings of this audit were reviewed with Data Manager and BMT/CT Quality Compliance Manager on 2018.

TABLE 1: PATIENTS SELECTED FOR AUDIT		
CRID	AUDITOR	DONOR and HSC SOURCE
		Allogeneic PBSC
		Allogeneic CBU
		Allogeneic CBU
		Allogeneic CBU
		Autologous PBSC
		Autologous PBSC
		Allogeneic PBSC
		Allogeneic BM
		Allogeneic BM
		Allogeneic BM

Note regarding patient selection: Patients receiving Autologous PBSC or Allogeneic BM were selected at random. To ensure reasonably even distribution of all forms audited by Donor and HSC source, first patient receiving Allogeneic PBSC and first three patients receiving CBU were manually selected. Auditor had no knowledge of number of forms reported or data complexity prior to selecting patients for audit.

Audit Findings and Recommendations:

Overview of audit findings is presented in table 2 below:

Table 2: overview of audit findings

Number of patients(CRIDS) audited	10
Total fields audited	2757
Number of errors (% Total errors)	31 (1.1%)
Total critical fields audited	383
Number of errors (% Critical errors)	9 (2%)
Total non-critical field audited	2374
Number of errors (%errors)	22 (0.1%)
Total Consents Reviewed	10
Total Consents signed	10

1. PRE-TRANSPLANT ESSENTIAL DATA FORMS

- HSCT date – 100% accurate. Of note: the planned HSCT date is recorded on the pre-TED and the actual HSCT date is recorded on the post- TED (i.e., any change in plan is recorded on the post-TED).
- Donor information – 100% accurate when compared to source documentation found in both the donor chart and stem cell lab chart.
- Clinical status of recipient prior to preparative regimen – 100% accurate when compared to source documentation
- Pre-HCT preparative regimen – 100% had accurate documentation. Source documentation is the BMT treatment plan.
- Diagnosis date & diagnosis for HSCT– documented accurately in 100% of the TEDS forms reviewed.

Findings:

1.1 Errors were identified in reporting of karyotyping and FISH results for 2 patients (CRID and # These two patients had complex cytogenetics report and nomenclature.

1.2 Data manager used default "standard" or "daylight savings" time value instead of the accurate one in the applicable fields.

1.1 Recommendation and Corrective Action:

- Results for 2 patients (CRID identified in this report were corrected. Corrective action for these 2 patients was implemented by 2018.
- Data manager to review cytogenetics results with a second team member to ensure accurate interpretation for future entries.
- Review already reported data and make corrections if needed. Estimated date for completion: 2018.

1.2 Recommendation and Corrective Action:

At the time of reporting data, data manager will distinguish between standard time and daylight savings, using the following website https://www.timeanddate.com/time/change/canada/ontario
For already reported data to CIBMTR: Data manager has reviewed and corrected all applicable fields in all forms reported in 2017 to ensure standard time and daylight savings time were used appropriately. Corrective action completed by 2018.

POST – TRANSPLANT ESSENTIAL DATA FORMS:

- *Initial engraftment date* – 100% accurate
- *Platelet engraftment date* – 100% accurate
- *GVHD data – 100% of TED forms accurate.*
- *New Malignancy, Lymphoproliferative or Myeloproliferative Disorder – 100% accurate with source documentation available when applicable.*
- *Survival status* – 100% accurate.
- *Post HSCT therapy* – Documented accurately in all cases where applicable.
- *Malignant disease evaluation for this HSCT* Accurate and source documentation available when applicable.
- *First relapse or progression after HSCT* – Documented appropriately in 100% of applicable cases; source documentation available.
- *Method of latest disease assessment – TED form completed accurately; source documentation available.*
- *Donor cellular infusion – 100% accurate, except for infusion times (as described above regarding errors for use of default for standard time and daylight savings).*

No Findings. No Recommendations.

2. INFORMED CONSENT:

Consent forms of recipients selected for this internal audit were audited for completion. All consent forms were signed by patient and/or authorized adult.

The has local REB approval for CIBMTR/NMDP Research Database protocol.

The is not participating in the Research sample repository protocol.

Findings:

In 2 of 10 consents (CRID # the date was incompletely recorded by the parent:

2.1 Patient CRID # - Parent had signed, and entered the time signed, but did not date the form. Staff physician who was involved in consent process and has signed and dated the consent form also documented the issue with the missing date associated with parent signature. No further action required.

2.2 Patient CRID # Parent had written day, month and time of consent, but not the year.

2.1 & 2.2 Recommendation and Corrective Action:

Issues with parent full completion of the consent forms was identified earlier in the CIBMTR reporting the process. Staff who is involved in consent obtaining is familiar with this issue and is now more cautious at checking consents for full completeness at the time of consent.

No corrective action is needed.

Practice Improvement Recommendations:

During the audit and the follow-up interview with the Data Manager it was identified that documentation of patients' GVHD status in source documents is not consistent. Variabilities exists in various source documents related to one patient and also varies between physicians. More consistent and standardized approach is recommended to be implemented in the future.

Auditor: _____ **Date:** 2018

Reviewed by:

Auditee (Data Manager):_____ _____ **Date:** 2018

Auditee Management: _____ ____ **Date:** 2018

BMT/CT Medical/Program Director: __ **Date:** 2018

BMT/CT Quality Manager: __ **Date:** 2018

Corrective Action Preventive Action Report

Initiator:	Date Initiated: 2018	CAPA #: 2018-01

Nonconformity/Issue/Trend Description:

As per FACT requirement, Internal Audit of data accuracy contained in the Transplant Essential Data Forms of the CIBMTR has to be performed. Internal Audit of data reported for 10 patients (approximately 10% sample size) transplanted in 2017 was performed on 2018. Errors were identified in 2 out of 10 audited patients for cytogenetics data reporting - karyotyping and FISH results.

Errors were identified for patient CRID # and patient CRID #

Classification	Origin		
☒ Corrective Action ☒ Preventive Action	☐ Mgt Review ☒ Internal/External Audit	☐ Complaint ☐ Safety Reporting	☐ Non-Conformance ☐ Other:

Investigation Results:

Data for two patients identified to have errors in cytogenetics data reporting were corrected immediately, 2018. These two patients had complex cytogenetics report and nomenclature. It was determined that errors were data interpretation errors, not transcription errors. Corrections for these two patients were made in collaboration with another BMT/CT team member.

Identify Root Cause:

Complexity of cytogenetics data.

CAPA Action Plan:

1. All already reported data for patients transplanted in 2017 will be reviewed by Data Manager and an additional team member for cytogenetics data accuracy reported to CIBMTR. Corrections will be made if needed.
   Estimated corrective action completion date – 2018.
2. Going forward, entries of cytogenetic data should be performed by Data Manager in collaboration with an additional BMT/CT team member. This will be an ongoing process until the assessment is made by the subsequent Internal Audit that such collaboration is no longer needed.

Describe plan for evaluating effectiveness:

During the next internal audit (sample size to be comparable with performed audit) verify accuracy of cytogenetics data and compare findings with previous, 2017 data audit.

CAPA Plan Approved: Signature:	Date: 2018

Completion Date of CA or PA:	Documentation Change: ☐ YES ☒ NO

CAPA Effective: ☐ Yes ☐ No Signature:	Date:
Final Approval by Director (signature):	Date: